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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/770,403

02/04/2004

Timothy P. Murphy

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EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

08/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/770,403

Applicant(s)

MURPHY, TIMOTHY P.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,8-14 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8-14 and 23-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 12, 2007 has been entered.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-6, 8-10, and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flesler et al (US 2002/0161414) in view of Ruiz (US 6,120,534). Flesler discloses a method of constricting the arteries leading to the small intestine with electrical stimulation but does not disclose placing a blood flow reducing device or an endograft inside the artery as claimed. However, Ruiz teaches that it was known to use physical restriction devices in arteries in order to restrict blood flow where needed; see

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the figures (particularly Figures 8A to 8C), the abstract, column 2, lines 5-58, and column 7, line 21 to column 8, line 16. Therefore, it is the Examiner's position that it would have been obvious to utilize the endograft device of Ruiz in conjunction with or in place of the electrical stimulation device of Flesler to provide a set degree of minimal constriction that can be varied with the electrical stimulation means or for the same reasons that Ruiz utilizes the same.

With regard to claims 3 and 8, the electrodes (200) of Flesler are devices placed around (i.e. in the area of) arteries of the small intestine including the superior mesenteric (110); see Figure 4. For this reason, the Examiner asserts that the claim language is clearly obvious over Flesler as modified by Ruiz.

With regard to claims 5 and 6, Flesler teaches putting electrodes in arteries leading to the small intestine. Since the gastroduodenal artery leads to the small intestine, the use of a constriction device therein is clearly suggested.

With regard to claim 12, Ruiz clearly teaches expanding the constrictor to adjust the amount of blood flow; see *supra*. For this reason, such would be obvious when utilized in Flesler's method.

With regard to claim 13, a "swellable material" is interpreted broadly to mean a material that is able to increase in size or expand in size or shape; see <http://encarta.msn.com/encnet/features/dictionary/DictionaryResults.aspx?refid=1861717507>. Clearly the middle portion of the Ruiz device is a material that can be increased in size and shape; see *supra*.

With regard to claim 14, the Examiner asserts that it would have been obvious to manage pain or discomfort by adjusting the constriction in order to maximize the benefit of the device where utilized.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Flesler and Ruiz as applied to claims 1, 3-6, 8-10, and 12-14 above, and further in view of Yurek et al (US 5,690,644). Flesler fails to disclose moving a sleeve over the endograft and removing the sleeve within the artery. However, Yurek teaches that it was known to utilize sleeves over stents with inner catheters; see Figure 1 and column 3, lines 46-58. Therefore, it is the Examiner's position that it would have been obvious to utilize a sleeve with the stent and catheter of Flesler for the same reasons that Yurek utilizes the same, in order reduce artery tissue damage during delivery or to better control expansion of the constrictor.

Claims 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Flesler et al (US 2002/0161414) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Flesler et al (US 2002/0161414) in view of Ruiz (US 6,120,534). Flesler anticipates the claim language where electrical stimulation is used to constrict the arteries leading to the small intestine; see paragraphs [0020], [0011], and [0113]-[0114]. The reduction is considered to be permanent, fixed, invariable, and continuous to the extent required because these terms are terms of relative degree. The Flesler can and is used for permanent, fixed, invariable, and continuous way at least for a period of time.

Alternatively, one may not consider these terms of degree met by Flesler because Flesler teaches that the amount of reduction can be varied and transient.

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However, Ruiz teaches that it was known to the artery treatment art to make blood flow reduction more permanent, fixed, invariable, and continuous; see the previously recited portions thereof. Therefore, it is the Examiner's position that it would have been obvious to utilize the Ruiz device in addition to the Flesler device to provide a set degree of minimal constriction that can be varied with the electrical stimulation means or for the same reasons that Ruiz utilizes the same.

Response to Arguments

The Applicant traverses the rejection by providing evidence, in non-affidavit form, that suggests advantages and disadvantages to a proposed obesity treatment method. However, this evidence was not considered persuasive with respect to the Section 103 rejection because it is considered disconnected to the issue(s) of patentability.

Specifically, it what treatment method was proposed to the NIH panel and whether that treatment was commensurate with the present claim scope. Furthermore, it was not clear what the skill level of the panel expects was in that it was not clear which of the at least 13 panel members actually evaluated the proposed treatment method. The panel members may have been aware of some devices and treatment method within the art but it was not clear whether they were particularly aware of patent literature; in particular, patents that were not practiced and turned into actual products and treatment within the field of endeavor. Additionally, the examiner does not know much about the panel's members so he cannot give their opinion, as far as patentability, much weight.

Moreover, there is no evidence that the panel actually evaluated the applied prior art against the claimed method as to determine novelty or obviousness. There is no evidence that the panel reviewed the patented claims and compared them to the applied prior art. It was noteworthy that the NIH responses make no mention of any of the applied prior art or of any patented method or product. In fact, the Applicant admits that ***"the NIH grant responses: (1) were prepared by a U.S. Government agency not concerned with patentability, but instead with safety and public health"***; see page 5, last paragraph of the response file July 12, 2007.

Therefore, since the NIH panel's opinions were disconnected with patentability, there were considered to be of little patentable significance. As a result, the Applicant's arguments in this regard were similarly considered unpersuasive.

In response to the traversal of the Flesler in view of Ruiz rejections that Flesler is not capable of controlling constriction (see the paragraph bridging pages 6 and 7 of the July 12, 2007 response), the Examiner asserts that a controller is used to apply electrical current so the amount of constriction can inherently be controlled. The Applicant's traversal makes it sound as if the Flesler device is so uncontrollable that it is not operable. However, since this same applied reference is not patented (US 6,600,953), the Examiner asserts that it is presumed operable.

The Applicant also traverses the rejections by arguing that improper hindsight was used to construct them. However, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of

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ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper.

See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/
Paul Prebilic
Primary Examiner
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